

PATENT Customer No. 22,852 Attorney Docket No. 3806.0046-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Hervé BOUCHARD et al.)) Group Art Unit: 1625)
Application No.: 08/162,984)) Examiner: B. Trinh
Filed: December 8, 1993))
For: TAXOIDS, THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM))))
Commissioner for Patents	

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached PTO SB/08. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement's fee of \$180.00, as specified by Section 1.17(p), should be charged to our Deposit Account No. 06-0916.

Copies of the listed foreign and non-patent literature documents are attached.

Copies of the U.S. patent publications are not enclosed.

01/24/2005 MMEKONEN 00000066 060916 08162984 02 FC:1806 180.00 DA With respect to the non-English language documents, Applicants submit the following comments:

- 1. <u>WO 94/10995</u> An English language Abstract of this document can be found on the front of this document.
- 2. <u>EP 0 827 745 B1</u> This document is believed to be related to U.S. Patent No. 5,728,687.
- 3. <u>WO 92/09589</u> An English language Abstract of this document can be found on the front of this document.
- 4. <u>WO 94/07878</u> An English language Abstract of this document can be found on the front of this document.
- 5. <u>EP 0 336 841</u> An English language Derwent Abstract for this document is submitted herewith.

Applicants respectfully request that the Office consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If the Office applies the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

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Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

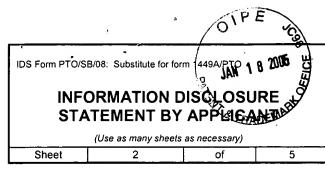
Dated: January 18, 2005

Thomas L. Irving Reg. No. 28,619

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	(Use as many sheets	as necessary)		Examiner Name	Ba Trinh	
Sheet	1	of	5	Attorney Docket Number	03806.0046-00000	

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Examiner	Cite No.1	Document Number	Issue or	Name of Patentee or	Pages, Columns, Lines, Where
Initials	No.	Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-4,507,217	03-26-1985	Sears	
		US-4,534,899	08-13-1985	Sears	
		US-4,857,653	08-15-1989	Colin et al.	
	<u>-</u> .	US-4,876,399	10-24-1989	Holton et al.	
		US-5,015,744	05-14-1991	Holton	
		US-4,892,735	01-09-1990	Harrap	
		US-5,136,060	08-08-1992	Holton	
		US-5,175,315	12-29-1992	Holton et al.	
		US-5,227,400	07-13-1993	Holton et al.	
		US-5,229,526	07-20-1993	Holton	
		US-5,243,045	09-07-1993	Holton et al.	
		US-5,250,683	10-05-1993	Holton et al.	
		US-5,254,580	10-19-1993	Chen et al.	
		US-5,254,703	10-19-1993	Holton et al.	
		US-5,262,409	11-16-1993	Margolis et al.	
		US-5,274,124	12-28-1993	Holton	
	•	US-5,283,253	02-01-1994	Holton et al.	
		US-5,284,864	02-08-1994	Holton et al.	
		US-5,284,865	02-08-1994	Holton et al.	
		US-5,294,637	03-15-1994	Chen et al.	
		US-5,294,737	03-15-1994	Ojima	
		US-5,319,112	06-07-1994	Kingston et al.	
-		US-5,336,785	08-09-1994	Holton	
		US-5,338,872	08-16-1994	Holton et al.	
		US-5,350,866	09-27-1994	Holton et al.	
		US-5,384,399	01-24-1995	Holton	
		US-5,399,726	03-21-1995	Holton et al.	
		US-5,405,972	04-11-1995	Holton et al.	
		US-5,415,869	05-16-1995	Straubinger et al.	
	-	US-5,430,160	07-04-1995	Holton	
		US-5,466,834	11-14-1995	Holton	
		US-5,484,809	01-16-1996	Hostetler et al.	
		US-5,489,601	02-06-1996	Holton et al.	
		US-5,494,683	02-27-1996	Liversidge et al.	

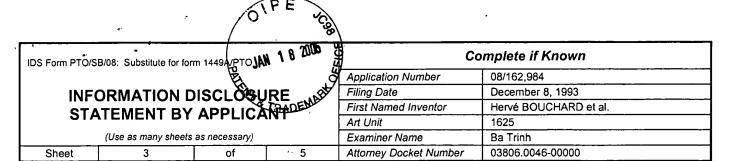


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First Named Inventor	Hervé BOUCHARD et al.			
Art Unit	1625			
Examiner Name	Ba Trinh			
Attorney Docket Number	03806.0046-00000			

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS						
US-5,532,363	07-02-1996	Holton				
US-5,532,388	07-02-1996	Bouchard et al.				
US-5,539,103	07-23-1996	Holton				
US-5,574,156	11-12-1996	Holton				
US-5,580,998	12-03-1996	Bouchard et al.				
US-5,587,489	12-24-1996	Holton et al.				
US-5,618,952	04-08-1997	Holton et al.				
US-5,635,531	06-03-1997	Chen				
US-5,637,732	06-10-1997	Holton et al.				
US-5,645,988	07-08-1997	Vande Woude et al.				
US-5,654,447	08-05-1997	Holton et al.				
US-5,710,287	01-20-1998	Holton et al.				
US-5,714,513	02-03-1998	Holton et al.				
US-5,717,115	02-10-1998	Holton				
US-5,721,268	02-24-1998	Holton et al.				
US-5,723,634	03-03-1998	Holton				
US-5,723,635	03-03-1998	Durand et al.				
US-5,728,687	03-17-1998	Bissery				
US-5,728,725	03-17-1998	Holton et al.				
US-5,728,850	03-17-1998	Holton et al.				
US-5,739,362	04-14-1998	Holton et al.				
US-5,760,219	06-02-1998	Holton et al.				
US-5,760,252	06-02-1998	Holton et al.				
US-5,814,658	09-29-1998	Bouchard et al.				

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

Examiner	Cite		Publication Date	Name of Patentee or	Pages, Columns,	Translation ⁶
Initials	No.1	Foreign Patent Document	MM-DD-YYYY	Applicant of Cited Document	Lines, Where	Hansiauon
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)			Relevant Passages or Relevant Figures Appear	
7.0	-	WO 92/09589	06-11-1992	Bourzat et al.		Abstract
	_	WO 92/19765	11-12-1992	Van Woude et al.		
>		WO 93/18751	09-30-1993	Rahman et al.		
-	•	WO 94/07878	04-14-1994	Commercon et al.		Abstract
	. `	WO 94/10995	05-26-1994	Bissery		
	-	WO 94/13655	06-23-1994	Hester et al.		



FOREIGN PATENT DOCUMENTS							
	WO 94/18164	08-18-1994	Ojima				
<u>, </u>	WO 94/26253	11-24-1994	Slater et al.				
	WO 94/26254	11-24-1994	Boni et al.				
	WO 96/00724	01-11-1996	Kelly et al.				
	EP 0 336 841	10-11-1989	Colin et al	Abstract			
	EP 0 604 910	07-06-1994	Golik et al.				
	EP 0 639 577	02-22-1995	Golik et al.				
,	EP 0 694 539	01-31-1996	Wong et al.				
	EP 0 827 745 B1	03-11-1998	Bissery	Counterpart to U.S. Patent No. 5,728,687			
-	EP 0 982 028 A1	03-01-2000	Bissery et al.				
,	EP 0 118 316 A2	09-12-1984	Sears				

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
		English language Derwent abstract for EP 0 694 539.	
		GUERITTE-VOEGELEIN et al., "Relationships between the Structure of Taxol Analogues and Their Antimitotic Activity," <i>J. Med. Chem.</i> 34:992-998 (1991).	
		KLEIN et al., "Synthesis of Ring B-Rearranged Taxane Analogs," J. Org. Chem., 59: 2370-2373 (1994).	
		ROSE, "Taxol: a Review of its Preclinical in vivo Antitumor Activity," Anti-Cancer Drugs, 3:4, Aug. 1992, pp. 311-321.	
		ROSE, "Preclinical Antitumor Acitivity of Tumors," Taxol Science and Applications, 1995, pp. 209-235.	
··· ·		VYAS et al., "Phosphatase-Activated Prodrugs of Paclitaxel," Taxane Antitumor Agents (an ACS Symposium), Mar. 13-17, pp. 124-137.	-
		VYAS et al., "Paclitaxel: A Unique Tubulin Interacting Anticancer Agent," Progress in Medicinal Chemistry, vol. 32, 1995, pp. 289-337.	
		SHELANSKI et al., "Microtubule Assembly in the Absence of Added Nucleotides," vol. 70, No. 3, pp. 765-768 (Mar. 1973).	
		de GÉRARD CHAUVIÈERE et al., "Chimie Organiuqe Biologique," Comptes Rendus Des Seances de L'Academie des Sciences, pp. 501-503 (Oct. 1981).	,
		KANT et al., "A Chemoselective Approach to Functionalize the C-10 Position of 10-Deacetylbaccatin III Synthesis and Biological Properties of Novel C-10 Taxol.RTM. Analogue," Bristol Myers Squibb Pharmaceutical Research Institute, vol. 35, No. 31, pp. 5543-5546 (Jun. 1994).	
		GREENE et al., "Protective Groups in Organic Synthesis," Wiley-Interscience Publication, Ch. 2, pp. 50-62 (1981).	
		CHEN et al., "Paclitaxel Structure-Activity Relationships and Core Skeletal Rearrangements," Chapter 18 from Taxane Anticancer Agents, pp. 247-2614 (Oct. 1994).	
		KINGSTON et al., "4.3 Chemical Reactivity," Progress in the Chemistry of Organic Natural Products, pp. 62-81 (1993).	
		ROWINSKY, E. et al., "The Clinical Pharmacology and Use of Antimicrotubule Agents in Cancer Chemotherapeutics," <i>Pharmacology & Therapeutics</i> , Vol. 52, No. 1, The Journal of The International Encyclopedia of Pharmacology and Therapeutics, (October 1991).	
		ROWINSKY, E. et al., "Sequences of Taxol and Cisplatin: A Phase I and Pharmacologic Study," J. of Clin. Oncology, Vol. 9, pp. 1692-1703 (1991).	
		BISSERY, M. et al., Abstract 2645, Proceedings of the AACR, Vol. 33, p. 443 (March 1992).	

Complete if Known IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPROXIMENT 08/162,984 Application Number Filing Date December 8, 1993 First Named Inventor Hervé BOUCHARD et al. Art Unit 1625 (Use as many sheets as necessary) Examiner Name Ba Trinh 03806.0046-00000 Attorney Docket Number Sheet

 NON PATENT LITERATURE DOCUMENTS	
COMMERCON et al., "Improved Protection and Esterification of Precursor Taxotere® and Taxol Side Chains," Tetrahedron Letters, 33(36):5185-5188 (1992).	
 CHEN et al., "Serendipitous Synthesis of a Cyclopropane-Containing Taxol Analog Via Anchimeric Participation of an Unactivated Angular Methyl Group," <i>J. Org. Chem.</i> , 58:4520-4521 (1993).	
BISSERY, M., et al., "Preclinical Profile of Docetaxel (Taxotere): Efficacy as a Single Agent and in Combination," Seminars in Oncology, Vol. 22, No. 6 (Suppl 13), pp. 3-16 (1995).	
BISSERY, M., et al., Abstract 1599, "Preclinical <i>In Vivo</i> Activity of Docetaxel Containing Combinations," <i>Proceedings of ASCO</i> , Vol. 14, p. 489 (1995).	•
MIRABELLI, C., et al., "A Murine Model to Evaluate the Ability of <i>In Vitro</i> Clonogenic Assays to Predict the Response to Tumors <i>In Vivo</i> ," <i>Cancer Res.</i> , Vol. 48, pp. 5447-5454 (1988).	
LLOMBART-CUSSAC, A., et al., Proceedings of ASCO, Vol. 16 (1997), Abstract No. 629.	
GELMON, K., et al., "Phase I Dose-Finding Study of a New Taxane, RPR 109881A, Administered as a One-Hour Intravenous Infusion Days 1 and 8 to Patients with Advanced Solid Tumors," <i>Journal of Clin. Oncology</i> , Vol. 18, No. 24, pp. 4098-4108 (2000).	
KURATA, T., et al., "Phase I and Pharmacokinetic Study of a New Taxoid, RPR 109881A, Given as a 1-Hour Intravenous Infusion to Patients with Advanced Solid Tumors," <i>Journal of Clin. Oncology</i> , Vol. 18, No. 17, pp. 3164-3171 (2000).	
BUDAVARI, S., et al., "Docetaxel," "The Merck Index, 13th Edition," Merck Research Laboratories, 3431, pp. 597-98, "Paclitaxel", p. 1251 (Ed. 2001).	
HARTLEY-ASP, B., "Estramustine-Induced Mitotic Arrest in Two Human Prostatic Carcinoma Cell Lines DU 145 and PC-3," <i>The Prostate</i> , Vol. 5, pp. 93-100 (1984).	
HORWITZ, S., et al., "Taxol: A New Probe for Studying the Structure and Function of Microtubes," <i>Cold Spring Harbor Symposia on Quantitative Biology,</i> Organization of the Citoplasm, Vol. XLVI, pp. 219-226 (1982).	
BISSERY et al., Abstract 50, "Preclinical <i>In Vivo</i> Evaluation of Docetaxel (Taxotere®) Containing Combinations," <i>Proc. of the Cytoskeleton and Cancer</i> , p. 50 (17-20 September 1995).	
LOPES, N. et al., "Assessment of Microtubule Stabilizers by Semiautomated in Vitro Microtubule Protein Polymerization and Mitotic Block Assays," <i>Cancer Chemother. and Pharm.</i> , Vol. 41, No. 1, pp. 37-47 (1997).	
JOHNSON, R. et al., "Taxol Chemistry. 7-0-Triflates as Precursors to Olefins and Cyclopropanes," Tetrahedron Letters, Vol. 35, No. 43, pp. 7893-7896 (1994).	
D'ARPA et al., "Topoisomerase-targeting antitumor drugs," Biochim. Biophys. Acta 1989, 989: 163-177.	
GUPTA et al., "Camptothecin-resistant Mutants of Chinese Hamster Ovary Cells Containing a Resistant Form of Topoisomerase I," Cancer Research, (1988 Nov. 15) 48 (22) 6404-10.	
 MUGGIA et al., "Phase I Clinical Trial of Weekly and Daily Treatment with Camptothecin (NSC-100880): Correlation with Preclinical Studies," Cancer Chemother. Rep. 1972, 56:515-521.	
 TSURUO et al., "Antitumor effect of CPT-11, a new derivative of camptothecin, against pleiotropic drug- resistant tumors in vitro and in vivo," Cancer Chemother. Pharmacol., 1988 21:71-4.	_
 RINGEL et al., "Studies with RP 56976 (Taxotere): A Semisynthetic Analogue of Taxol," J. Natl. Cancer Inst., 1991, 83:288-291.	
HOLMES et al., "Phase II Trial of Taxol, an Active Drug in the Treatment of Metastatic Breast Cancer," J. Natl. Cancer Inst., (1991 Dec 18) 83 (24) 1797-805.	
 BISSERY et al., "Docetaxel (Taxotere®): a review of preclinical and clinical experience. Part I: preclinical experience," Anti-Cancer Drugs, 1995, 6: 339-368.	
LEUPIN et al., "Application of ¹³ C(_{a1})-half-filtered [¹ H, ¹ H]-NOESY for studies of a complex formed between DNA and a carbon-13-labeled minor-groove-binding drug," Chemical Abstracts, vol. 113, No. 75e, (1990).	
ACTA Crystallograph. Sect. C: Crystal Structure Commun., vol. C46, No. 5, 190, pp. 781-784, (1990).	

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Sheet	5	of	5	Attorney Docket Number	03806.0046-00000	

Examiner	Dat	e
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.